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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,146	08/08/2002	Karl-Christian Gallert	29988/AX98115	2319

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,146

Applicant(s)

GALLERT ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The preliminary amendment filed April 6, 2001, has been received and entered.

Claims 1-12 are pending and are examined on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 6-12 are rejected under 35 U.S.C. 101 because they are directed to non-statutory subject matter. With respect to claims 1-3, the claims encompass naturally occurring products, such as starch. This is clearly evidenced by the fact that claim 3 recites "a nature-identical polymer." Products of nature are not patentable subject matter under § 101. Similarly, with respect to claims 6-12, those claims encompass products comprised of a single ingredient, the polyglucan, or glucose polymer, of claim 1. Because claim 1 encompasses naturally occurring products, and because claims 6-12 do not require any ingredients in addition to the polymer of claim 1, claims 6-12 also encompass naturally occurring products, and are therefore not patentable subject matter under § 101.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the product made according to the disclosure is composed of a single monomer, glucose. While the claims encompass the production of derivatives of the glucose polymer, there is no description whatsoever in the specification of the structures of the glucose polymer when it is incorporated into the graft, block, and other polymers recited in claim 4. Because the specification fails to provide any description of the structures of the polymers recited in claim 4, including what moieties other than glucose may be present therein, a holding of lack of proper written description is required.

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Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the product made according to the disclosure is composed of a single monomer, glucose. While the claims encompass the production of derivatives of the glucose polymer, there is no discussion whatsoever in the specification, in the single example or otherwise, regarding how the glucose polymer is to be incorporated into the graft, block, and other polymers recited in claim 4, particularly in view of the fact that the polymer types in claim 4 require different monomers, and the disclosed process uses only one monomer, glucose. Because the specification fails to provide any disclosure regarding how to make the polymers recited in claim 4, the artisan of ordinary skill would have to undertake a trial and error process to determine what other polymers, monomers, reaction conditions, reactants, and products would be useful to practice the invention recited in claim 4. Such an unguided trial and error process, with respect to virtually every parameter required for

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practicing claim 4, must be considered undue experimentation. A holding of non-enablement is clearly required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is not clear what process is being used to prepare the polyglucan or glucan derivative. While the claim does refer to product being "obtained from" the enzymes, it is not clear what the enzymes are acting on, or what actual steps are required for the product to be obtained. Generally, enzymes require specific substrates for anything to be obtained from them.

Claim 2 is indefinite because it requires the polyglucan of claim 1 to have a particular amino acid sequence. However, the product of claim 1 is a polymer of glucose. Therefore the product of claim 1 does not contain amino acids, and cannot have an amino acid sequence.

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Claim 4 is confusing because it is not clear how a polyglucan derivative, composed of a single monomer of glucose or a derivative, can possibly be any of the listed polymer types.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 6-12 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Okada et al (U.S. Pat. 4,454,161) or Boyer et al (Biochemistry 16(16):3693-3699 (1977)) or Rumbak et al (J. Bacteriol. 173(21):6732-6741 (1991)) or Kossman (WO 95/31553). Note that these references are not relied on in combination, and none of the references is intended to overcome a shortcoming in any of the other references.

The claims encompass products made by the action of either a polyglucan sucrase, or a polyglucan amylosucrase and a transferase which may be a glycosyltransferase. Proper reference to the specification makes it clear that the term polyglucan sucrase means the same thing as amylosucrase. Amylosucrase produces amylose, which is an essentially linear glucose polymer having α -1,4 bonds linking the glucose monomers. Proper reference to the specification makes it clear that the

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transferase may be an enzyme which introduces α -1,6 branch points on to the linear α -1,4 amylose molecule. Thus, the product resulting from the claimed process may be amylose, or an amylose molecule having α -1,6 branch points.

Each of the cited references discloses products which appear to be identical to the presently claimed product, based on the fact that the prior art products result from the action of a branching enzyme on an amylose molecule. See Okada, column 1, line 64 to column 2, line 4, disclosing not only amylose as a known product, but also the use of a branching enzyme to insert α -1,6 branch points onto the amylose molecule. See also Boyer et al, at pages 3696 to 3698, especially Table II, disclosing the insertion of α -1,6 branch points onto amylose. In particular note the production compounds from the simultaneous action of phosphorylase a (an amylose-producing enzyme) and the branching enzyme. Boyer page 3697. See also Rumbak page 6738, last full paragraph before Discussion section. See also Kossman's discussion, at pages 1 and 2, of the production of amylose from amylosucrase, and the applicability of the so-produced amylose to the utilities recited in claims 6-12.

Lastly, note that the glycosidic bond between sugar monomers in each of the cited references is an ether bond, as required by claim 3. Also, with respect to claims 6-12, none of

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those claims requires any ingredient other than the glucose polymer. Claims 3 and 6-12 are therefore properly included in the anticipation rejection.

While the claims are considered to be anticipated by the cited references for the reasons discussed above, the current claim language is of unclear scope. However, even if the reference products and the claimed product are not one and the same and there is, in fact, no anticipation, the reference products, nevertheless, would have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the claimed products are those resulting from enzymes having the same activities as the enzymes in the cited references.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Regarding the propriety of this type of alternative rejection, note that MPEP § 2113 states that:

. . . [w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then

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obtain prior art products and make physical comparisons therewith. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972).

MPEP § 2113 also clearly states that

'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature' than when a product is claimed in the conventional fashion. *In re Fessmann*, 180 USPQ 324 (CCPA 1974)."

Claims 1-3 and 5-12 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Büttcher et al (J. Bacteriol. 179(10):3324-3330 (1997)).

As discussed above, the claims encompass products made by the action of either a polyglucan sucrase, or a polyglucan amylosucrase and a transferase which may be a glycosyltransferase. Proper reference to the specification makes it clear that the term polyglucan sucrase means the same thing as amylosucrase. Amylosucrase produces amylose, which is an essentially linear glucose polymer having α -1,4 bonds linking the glucose monomers. Proper reference to the specification makes it clear that the transferase may be an enzyme which introduces α -1,6 branch points on to the linear α -1,4 amylose molecule. Thus, the product resulting from the claimed process

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may be amylose, or an amylose molecule having α -1,6 branch points.

Büttcher discloses a product which appears to be identical to the presently claimed product, based on the fact that the prior art products result from the action of a branching enzyme on an amylose molecule. See page 3327, discussing the production of branched polymers from amylosucrase-expressing *E. coli*, which also expresses glycogen branching enzyme:

XL1-Blue cells transformed with pAS3, however, did not form the halo surrounding the colonies, and furthermore, the glucans formed in these cells had an altered iodine staining pattern from blue to brown (Fig. 1 quadrant 3). This can be taken as a clear indication of the intracellular localization of the glucans (and the amylosucrase). **The iodine staining indicates that these glucans are branched**, probably due to the action of the glycogen branching enzyme (GlgB) which is present in *E. coli*. (Emphasis added.)

Thus, for the reasons discussed above with respect to the Okada, Boyer and Rumbak references, Büttcher is considered to anticipate claims 1-3 and 6-12. Moreover, with respect to claim 5, Büttcher clearly discloses that the amylosucrase was combined with a branching enzyme, within the transformed cell, to produce the branched glucan.

While the claims are considered to be anticipated by the cited references for the reasons discussed above, the current claim language is of unclear scope. However, even if the

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reference products and the claimed product are not one and the same and there is, in fact, no anticipation, the reference products, nevertheless, would have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the claimed products are those resulting from enzymes having the same activities as the enzymes in the cited references.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 1-3 and 6-12 are rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Akkara et al (U.S. Pat. 6,063,916).

In addition to the products discussed above, the claims encompass products which are made by the action of a polyglucan amylosucrase and a transferase which may be a protease. In particular note the requirement in claim 3 that the product is an ester. Akkara discloses that ester moieties can be introduced by the transesterification activity of a protease, which may be considered a transferase, on to amylose molecules. See, e.g., abstract. Because the prior art products are the

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same as those which would result from the action of a protease and amylosucrase, a holding of anticipation is required.

While the claims are considered to be anticipated by the cited reference, the current claim language is of unclear scope. However, even if the reference products and the claimed product are not one and the same and there is, in fact, no anticipation, the reference products, nevertheless, would have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that the claimed products are those resulting from enzymes having the same activities as the enzymes in the cited references.

Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kossman (WO 95/31553) in view of Boyer et al (Biochemistry 16(16):3693-3699 (1977)), Rumbak et al (J. Bacteriol. 173(21):6732-6741 (1991)) and Okada et al (U.S. Pat. 4,454,161).

As discussed above, Kossman discloses the production of amylose-type compounds using amylosucrase, and the applicability

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of those compounds to the utilities recited in claims 6-12.

Kossman differs from the claims in failing to disclose the process recited in claim 5, wherein the amylosucrase is combined with a transferase. However, as discussed above, each of Boyer and Rumbak disclose that starch-like or glycogen-like compounds can be produced by combining a branching enzyme, which may be a transferase, with an enzyme that produces a linear α -1,4 glucan amylose-type compound. Moreover, Okada discloses (columns 1 and 2) that compounds resulting from the action of branching enzymes on amylose have utility in food applications.

Thus, the artisan of ordinary skill performing the amylose production of Kossman clearly would have reasonably expected from Boyer and Rumbak that branching enzymes would have introduced branch points on Kossman's polysaccharide. The artisan of ordinary skill would have been motivated by Okada to have introduced those branch points on to Kossman's linear saccharides to have afforded the utilities disclosed by Okada. Further motivation would have been derived from the reasonable expectation that saccharides resulting from such a process would have found applicability in the same manner as starch, as recited in claims 6-12. A holding of obviousness is therefore required.

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No claims are allowed. U.S. Pat. 6,699,694, is cited to further show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'Francisco C Prats', with a long horizontal flourish extending to the right.

Francisco C Prats

Primary Examiner

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FCP